UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 13, 2024

AVITA Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39059**	**85-1021707**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
28159 Avenue Stanford Suite 220 Valencia, California		**91355**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 661 367-9170

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	RCEL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 13, 2024, AVITA Medical, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description of Exhibit**
99.1	Press release titled “AVITA Medical Reports First Quarter Financial Results"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVITA Medical, Inc.

Date: May 13, 2024

By: /s/ Donna Shiroma

Donna Shiroma
General Counsel

Exhibit 99.1

AVITA Medical Reports First Quarter Financial Results

VALENCIA, Calif., May 13, 2024 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), a commercial-stage regenerative medicine company focused on first-in-class devices for wound care management and skin restoration, today reported financial results for the first quarter ended March 31, 2024.

Financial Results and Recent Business Updates

- Commercial revenue increased approximately 5.8% to $11.1 million compared to the same period in 2023
- Gross profit margin of 86.4%
- Launched PermeaDerm, a co-branded biosynthetic wound matrix, in the U.S. on March 23, 2024

“We believe we have taken the necessary measures to invigorate our burns business and improve our commercial sales process to return to sustained growth," said Jim Corbett, AVITA Medical Chief Executive Officer. “We remain dedicated to establishing RECELL as the standard of care for burn and full-thickness skin defects. Simultaneously, we are actively transforming AVITA Medical into a broad wound care business by expanding our portfolio to address the full spectrum of clinical needs. We are confident that our strategic initiatives to transform our business will enhance accessibility and reach more patients."

Future Milestones

- RECELL GO, a device which provides consistent disaggregation of skin to produce RECELL Spray-On Skin Cells, is currently undergoing a 180-day interactive review by the U.S. Food and Drug Administration under the Breakthrough Devices Program; the 180-day period will end on May 30, 2024
- Plan to submit a PMA supplement for RECELL GO mini, which is designed to address smaller wounds. This submission will fall under the Breakthrough Device designation, which has been granted to RECELL for burns, RECELL for full-thickness skin defects, RECELL for repigmentation of stable depigmented vitiligo lesions, and RECELL GO
- Expect to submit both our post-market study (TONE) treating patients with stable vitiligo, and separate health economics study for publication by year-end

Financial Guidance

- Commercial revenue for the second quarter 2024 is expected to be in the range of $14.3 to $15.3 million
- Commercial revenue for the full-year 2024 is expected to be in the lower end of our previously provided guidance range of $78.5 to $84.5 million, reflecting growth of approximately 57% at the lower end of the range over the full-year 2023
- Expect to achieve previously given guidance of cashflow break even and GAAP profitability no later than the third quarter of 2025

"We acknowledge the significant cash utilization this quarter, however we remain confident in our financial stability and our ability to reach cashflow break even as guided," said David O'Toole, Chief Financial Officer of AVITA Medical. "It's important to note that the cash use was driven by several non-recurring items, including expenses incurred related to our distribution agreement with Stedical, totaling approximately $4.0 million for inventory purchases and other costs. Of this amount, approximately $3.1 million represents inventory that we will recover through future product sales, with gross sales in the range of $6 million."

First Quarter 2024 Financial Results

Our commercial revenue, which excludes Biomedical Advanced Research and Development Authority (BARDA) revenue, increased by approximately 5.8% to $11.1 million in the three-months ended March 31, 2024, compared to $10.5 million in the same period in 2023.

Gross profit margin was 86.4% compared to 84.2% in the corresponding period in the prior year.

Total operating expenses for the quarter were $26.8 million, compared to $19.4 million in the same period in 2023. The increase in operating expenses is primarily attributable to an increase of $6.1 million in sales and marketing expenses due to employee-related costs, including salaries and benefits, commissions, professional fees, and travel expenses, collectively, as a result of the expansion of our commercial organization to support our growing commercial operations in the second quarter of 2023. G&A expenses increased by $0.7 million as a result of higher salaries and benefits, partially offset by lower stock-based compensation. In addition, the increase in operating expenses included an increase of $0.6 million in R&D costs, which was primarily due to employee compensation costs of the team of Medical Science Liaisons.

Other income/expense, net increased by $0.8 million of expense, compared to the same period in 2023, as we recognized $0.4 million and $0.9 million in expense for non-cash charges due to the change in fair value of the debt and the warrant liability, respectively. These expenses were offset by an increase of approximately $0.5 million in income related to our investment activities and other income.

Net loss was $18.7 million, or a loss of $0.73 per basic and diluted share, compared to a net loss of $9.2 million, or a loss of $0.37 per basic and diluted share, in the same period in 2023.

BARDA income consisted of funding from the Biomedical Advanced Research and Development Authority, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C.

Webcast and Conference Call Information

AVITA Medical will host a conference call to discuss its financial and business results on Monday, May 13, 2024, at 1:30 p.m. Pacific Time (being Tuesday, May 14, 2024, at 6:30 a.m. Australian Eastern Standard Time). To access the live call via telephone, please register in advance to receive dial-in details and a personal PIN using the link here. A simultaneous webcast of the call will be available via the Company's website at https://ir.avitamedical.com/events-and-presentations.

About AVITA Medical, Inc.
AVITA Medical® is a commercial-stage regenerative medicine company transforming the standard of care in wound care management and skin restoration with innovative devices. At the forefront of our platform is the RECELL® System, approved by the Food and Drug Administration for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. RECELL harnesses the regenerative properties of a patient's own skin to create Spray-On Skin™ Cells, delivering a transformative solution at the point-of-care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes. AVITA Medical also holds the exclusive rights to market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, in the United States.

In international markets, the RECELL System is approved to promote skin healing in a wide range of applications including burns, full-thickness skin defects, and vitiligo. The RECELL System is TGA-registered in Australia, has received CE-mark approval in Europe, and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are subject to significant risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements.

Forward-looking statements generally may be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," and similar words or expressions, and the use of future dates. Applicable risks and uncertainties include, among others, the timing and realization of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company's control. These statements are made as of the date of this release, and the Company undertakes no obligation to publicly update or revise any of these statements, except as required by law. For additional information and other important factors that may cause actual results to differ materially from forward-looking statements, please see the "Risk Factors" section of the Company's latest Annual Report on Form 10-K and other publicly available filings for a discussion of these and other risks and uncertainties.

Investor & Media Contact:
Jessica Ekeberg
Phone +1-661-904-9269
investor@avitamedical.com
media@avitamedical.com

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

AVITA MEDICAL, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	As of	
	March 31, 2024	**December 31, 2023**
ASSETS	(unaudited)	(audited)
Cash and cash equivalents	$ 16,951	$ 22,118
Marketable securities	51,232	66,939
Accounts receivable, net	7,081	7,664
BARDA receivables	28	30
Prepaids and other current assets	3,523	1,659
Inventory	7,171	5,596
Total current assets	85,986	104,006
Plant and equipment, net	4,297	1,877
Operating lease right-of-use assets	3,275	2,440
Corporate-owned life insurance ("COLI") asset	2,880	2,475
Intangible assets, net	542	487
Other long-term assets	401	355
Total assets	$ 97,381	$ 111,640
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	4,477	3,793
Accrued wages and fringe benefits	5,803	7,972
Current non-qualified deferred compensation ("NQDC") liability	429	168
Other current liabilities	1,153	1,266
Total current liabilities	11,862	13,199
Long-term debt	41,301	39,812
Non-qualified deferred compensation liability	3,913	3,663
Contract liabilities	349	357
Operating lease liabilities, long term	2,532	1,702
Warrant liability	4,028	3,158
Total liabilities	63,985	61,891
Non-qualified deferred compensation plan share awards	827	693
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,789,051 and 25,682,078, shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at March 31, 2024 and December 31, 2023	-	-
Company common stock held by the non-qualified deferred compensation plan	(944)	(1,130)
Additional paid-in capital	353,205	350,039
Accumulated other comprehensive loss	(3,068)	(1,887)
Accumulated deficit	(316,627)	(297,969)
Total stockholders' equity	32,569	49,056
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	$ 97,381	$ 111,640

AVITA MEDICAL, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three-Months Ended	
	March 31, 2024	**March 31, 2023**
Revenues	$ 11,104	$ 10,550
Cost of sales	(1,513)	(1,667)
Gross profit	9,591	8,883
BARDA income	-	627
Operating expenses:		
Sales and marketing	(12,640)	(6,540)
General and administrative	(8,963)	(8,295)
Research and development	(5,194)	(4,586)
Total operating expenses	(26,797)	(19,421)
Operating loss	(17,206)	(9,911)
Interest expense	(1,356)	(4)
Other income (expense), net	(66)	725
Loss before income taxes	(18,628)	(9,190)
Income tax expense	(30)	(30)
Net loss	$ (18,658)	$ (9,220)
Net loss per common share:		
Basic and Diluted	$ (0.73)	$ (0.37)
Weighted-average common shares:		
Basic and Diluted	25,637,783	25,202,088